# 2ar

## Case

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# 1ar

## Case

### overview

Biocolonialism is an institutionalized extension of settlerism that is legitimized by MNCs through the piracy of traditional Indigenous knowledge under the protections of patents. This creates a power imbalance that causes cultural genocide in line with the notion of terra nullius.

The plan solves – it ends patents on medicines derived from Indigenous knowledge which serves as a termination of the “ethical right” to Indigenous knowledge that MNCs believe they have over the “global commons” of Indigenous land and property. Obviously, the plan does not end the sum total of settlerism, but it’s a step in the right direction that resolves an instance of it which justifies perm do aff then alt.

### Lbl

Backlash

1] durable fiat –

2] all nations – creates international pressuere & means US cant pull out

3] ev ab covid waiver not plac

## K

Framework

Ecohawk &drew -

**Incrementalism is good --- there have been times where native land has been carved out so working within the state is good for natives. This also proves their antagonism claim is false since empirical gains are possible**

#### The 1NC is the fixates land with identity – ontopology causes genocide

Mulaj 17, Klejda. "Violence of war, ontopology, and the instrumental and performative constitution of the political community." Review of International Studies 44.1 (2017): 64-82.Senior Lecturer in International Relations, Department of Politics, University of Exeter

In the prevailing interpretations of conflict and war there is a limited realisation that violence of war, on which construction of the political community is grounded, is enabled by a settled, modern norm of international society, namely the norm of territorial and cultural alignment with its nexus between sovereignty, security, and identity.46 The congruity of territorial boundaries of modern states with the cultural identity of their population is an attribute of the ideology of nationalism. Progressively consolidating its dominant position in Western Europe since the French and American revolutions, this ideology has swept the globe injecting into politics a profoundly significant ideal, the principle that national and state boundaries should coincide, i.e., that the state should be nationally homogenous, and the nation should be politically united.47 What needs emphasising is that the ultimate goal of nationalism—the establishment of a nationstate—requires political and social processes that cannot easily be detached from violence. This is because instituting the primacy and will of the nation as a source of political legitimacy requires social homogenisation—cultural, linguistic and frequently religious unity—which can be attained only by violent means, physical and/or symbolic.48 The naturalisation of the nexus of territory and identity requires a great deal of work and necessitates the worst violence. David Campbell rightly notes that the idea that the national community requires the nexus of demarcated territory and fixed identity has been complicit in, and necessary for, the conduct of war. The reason for this is that ‘inscribing the boundaries that make the installation of the nationalist imaginary possible requires the expulsion from the resultant “domestic” space of all that comes to be regarded as alien, foreign, and dangerous. The nationalist imaginary thus demands a violent relationship with the other’. 49 It is this conjunction of territory with population identification that gives rise to an order of representation that—with Jacques Derrida—Campbell understands in terms of ontopology.50 Reflecting on the violence ensuing the end of the Cold War, Derrida opined that: Inter-ethnic wars … are proliferating, driven by an archaic phantasm and concept, by a primitive conceptual phantasm of community, the nation-State, sovereignty, borders, native soil and blood. Archaism is not a bad thing in itself, it doubtless keeps some irreducible resource. But how can one deny that this conceptual phantasm is, so to speak, made more outdated than ever, in the very ontopology it supposes, by teletechnic dis-location? (By ontopology we mean an axiomatic linking indissociably the ontological value of present-being [on] to its situation, to the stable and presentable determination of a locality, the topos of territory, native soil, city, body in general).51 This section emphasises the circular nature of the relationship between ontopology and the instrumental aspect of violence, in the sense that not only has ontopology inspired some of the most exclusivist and instrumentally violent forms of human behaviour, but ontopology has been applied—too—to justify use of violence to enact an ontopological goal. For example, ethnic cleansing—forced expulsion of minorities, even genocide—intentional extermination of targeted ‘others’—have been a result of the above logic, i.e., the ontopological conjunction of territory and identity driven by the conceptual phantasm of national community, in most cases justified on the grounds of securing security of the state and the nation that provides its [i.e., state’s] source of political legitimacy. The twentieth century may be characterised as an ethnic cleansing century given the massive forced movement of peoples, and genocides from that of the Armenians, to the Holocaust, to the Tutsis, to the Bosnian Muslims—virtually all rationalised by ontopological interpretations that essentialise congruence of territory with identity of population that control it, interpretations that are justified by a conception of security that prioritises the nation state as the referent of security. 52 What is even more perplexing is the fact that the privileging of the nation state in terms of the provision of security has not only been embraced as a policy option, but has found the backing also of international legal experts. For example, according to International Law Professor Ian Brownlie, the expulsion of fourteen million Germans in the aftermath of the Second World War ‘may be justified as a part of the anctions and measures of security imposed by the principal members of a coalition which had fought a lawful war of collective defence against Nazi Germany’. 53 In his view, the act of expulsion was justified because the Allied Powers sought to prevent future threats to peace and security.54 The ontopological rationale of violence has permeated both the structures of intelligibility and response strategies that are supposed to contain violence. In point of fact, adherence to ontopological assumptions has frequently underlined international community’s responses to violent conflicts which, in turn, have either been conducive to more violence or have strengthened the nationalists’ imaginery of phantasm of national community, borders, native soil, blood, body in general—as Derrida noticed55—and its (implied) nexus between territory and identity. International diplomacy and Great Powers’ foreign policies have been amongst the most important sites via which nationalised conceptions of political community have affirmed and materialised. Suffice it to mention two representative categories of policy responses, namely the so-called population exchanges/transfers, and partition of territory.

The alt –

1] perm do both – af is an instantiation of the alt – form of decolonization where people get off the land

2] perm do aff then cp – creates conditions

**3] Materialism DA – alt forces all settlers to get off the land, including lower income, refugees, and minorities who can’t afford to, it’ll destroy the livelihoods of millions**

**4] Alt fails – no standard of action if indigenous disagree abt how decol and land divisions work, means you don’t know what happens in the world of the alt**

**5] doesn’t solve case – mncs j leave colonized nations but continue biocolonialism from other places**

**The links –**

# 1ac

### 1AC -- Biocolonialism

#### Biocolonialism is an institutionalized *global form* of “*dispossession and conquest*” perpetuated at the will of multinational corporations through the piracy of traditional knowledge and resources in the name of “intellectual property rights” and “international patents”.

**Breske ’18** [Ashleigh, visiting assistant professor of international studies in the global politics and societies (GPS) department @ Hollins University. She earned her Ph.D. in planning, governance, and globalization at Virginia Tech, her M.A.L.S. in social sciences with a focus on Roman history from Hollins University, and her B.S. in biology with a concentration in classical studies and chemistry. Her current research explores how institutions and cultural values mediate changes in repatriation policy for indigenous cultural property, “Biocolonialism: Examining Biopiracy, Inequality, and Power”, Spectra, 6(2), pp.58–73. DOI: http://doi.org/10.21061/spectra.v6i2.a.6]//pranav

Through examples of epistemic exploitation and a review of current literature on biocolonialism, this paper will highlight issues of indigenous knowledge and resource appropriation and how they relate to neoliberal economic practices. According to Lorenzo Veracini, the least visible types of colonial subjugation, like informal colonialism and trade imperialism, are the most resistant to change.i **This is especially true for biocolonialism, which arises through the dominant discourse of neoliberal economic practices around the world.** This form of colonialism is based on the exploitation and extraction of traditional resources and knowledge through western conceptions of property ownership. Neoliberalism has created a polarization in the world through conflicts between ethnicities and socio-economic levels, resulting in a dichotomy between the Global North and the Global South. **Concepts of western legal practices, intellectual property rights, national property laws, and biotechnology innovations create a system of biocolonialism with the dominant North capitalizing on these policies and practices.**ii **This has adversely affected the Global South in many ways and acts as an ideology promoting profit and economic growth at the expense of the marginalized.** The shift to neoliberalism has increased the divide between the developed and developing world and the “ideology of the market, and the omnipresence of market forces, have left an indelible mark on the western conception of knowledge.”iii **Power is often in the hands of transnational corporations and lobbyist groups with the global economy becoming larger than individual nation-state economies.**iv Cori Hayden theorizes that bioprospecting is “an important site for thinking about how neoliberalism works.”v For Hayden, **biopiracy is an institutionalized practice garnering transnational capital**. In other words, the opening of the market on biodiversity is argued to be both a development strategy and an argument for conservation within an economic framework. For example, in Peru, foreign corporations have filed more than 11,690 patents on natural resources traditionally used by indigenous communities.vi **Corporate interest in medicinal plants and seeds stems from long-term economic goals.** This example illustrates the current trend of outside transnational corporations showing an interest in traditionally-used medicinal plants and seeds. **Within the globalized economy, free trade agreements create a power imbalance between multinational corporations (MNCs) and the indigenous communities holding traditional knowledges and resources.** **Since indigenous knowledge is disseminated among the community and no one person owns it in the western, legal sense,vii MNCs use bioprospecting projects in areas with rich biodiversity for future development of products.**viii It has been found that bioprospecting success rates greatly increase with the inclusion of indigenous knowledge or local guidance. These endeavors are financed as exploratory enterprises to find aspects of biodiversity and indigenous knowledge as resources that can be patented and used for future development. **Bioprospecting can be considered a form of colonization using a “knowledge-based economy” with profit sought through marginalized peoples and their traditional resources**.ix But, according to Hayden, **“[b]ioprospecting is the new name for an old practice: it refers to corporate drug development based on medicinal plants, traditional knowledge, and microbes culled from the “biodiversity-rich” regions of the globe—most of which reside in the so-called developing nations.”** (Hayden 2003, 1). **Bioprospecting can quickly lead to biopiracy, or the appropriation of traditional knowledge and natural resources without due compensation**.x Biopiracy—and by extension, the intellectual property and patent system—is essentially a new apparatus of power used by MNCs. Bioprospectors make claims on biological resources based on the assumption that the resources are available and open to everyone.xi **Initially, corporations present themselves as the protectors and innovators of these “universally” valuable resources.** They claim that if it were not for their investments, the information and original sources might be lost. **However, it was only after the development of international patents and free trade agreements that indigenous groups understood their exclusion from the economic yields gained by utilizing their knowledge.**xii Essentially, **biocolonialism, in the form of pharmaceutical and agricultural industry development by transnational corporations, is a “continuation of the oppressive power relations that have historically informed the interactions of western and indigenous cultures, and part of a continuum of contemporary practices that constitute forms of cultural imperialism.”**xiii More simply**, it is a form of dispossession and conquest through the lens of neoliberalism**.

#### Traditional patent law and IPP *legitimize* biopiracy’s control over dominated subjects, turning them into capital.

**Breske 2** [Ashleigh, visiting assistant professor of international studies in the global politics and societies (GPS) department @ Hollins University. She earned her Ph.D. in planning, governance, and globalization at Virginia Tech, her M.A.L.S. in social sciences with a focus on Roman history from Hollins University, and her B.S. in biology with a concentration in classical studies and chemistry. Her current research explores how institutions and cultural values mediate changes in repatriation policy for indigenous cultural property, “Biocolonialism: Examining Biopiracy, Inequality, and Power”, Spectra, 6(2), pp.58–73. DOI: http://doi.org/10.21061/spectra.v6i2.a.6]//pranav

**Through biopiracy, outside corporations and nations can quickly take resources and secure their control through international intellectual property rights and patents.** **The legitimation for these corporations stems from this westernized, neoliberal economy and the reduction in trade barriers that benefits the wealthier areas of the world at the expense of marginalized peoples**. Power over these populations becomes normalized as a conception of power over dominated subjects. Indigenous communities are generally smaller populations that remain on the margins within the nation-state until they are found to have economic value. Peripheral governance then becomes more pervasive in their lives under neoliberalism and the erosion of international trade barriers and increases in foreign investors. Under neoliberalism, market rationality is extended to all aspects of life. According to Wendy Brown, and her reading of Weber, there is nothing outside of the market. This is a system that allows for transnational entities to have greater control than individual sovereignties. The deregulation of the market, the elimination of tariffs and social safety nets, and an increase in the decimation of the environment and marginalized cultures are all hallmarks of neoliberalism.xvii **When societies and their traditional resources are incorporated into the economy, they become a form of capital**. Essentially, in relation to resources and traditional knowledge, neoliberalism’s desire for profit creates a political tension between national interests and globalized capital.xviii

#### This represents a form of *cultural genocide* of Indigenous peoples in line with the notion of terra nullius – anything else relies on Western preoccupations with objectivity that ignores the communal nature of Indigenous “ownership”.

Diver ’04 [Alice, Dr Alice Diver is a Senior Lecturer in Law at Liverpool John Moores University, who publishes in the areas of adoption, human rights, property law, and law in literature. She joined LJMU in September 2018, having worked as a Senior Law Lecturer and Programme Leader for the LLB (Law and Criminology) and as a Senior (Faculty) Fellow for L& T at EHU (2015-2018). Prior to that she was employed as a Lecturer in Law/TJI Associate Researcher, and Course Director for the LLB programmes (Magee campus) at Ulster University, N Ireland (2000-2015). She previously worked as a Solicitor in N Ireland in private practice (1989-1995) and as an Associate Lecturer in Law at NWRC (1993-2004). She is an alumna of Queen's University Belfast (LLB, 1984; LLM (Dist.), 2004) and gained a First class BA Hons in English Literature from Ulster University in 2017. She is the author of a 2013 monograph on origin deprivation, closed records and familial contact in adoption and surrogacy entitled 'A Law of Blood-ties: The 'Right' to Access Genetic Ancestry' (Springer) which is based upon her PhD (Ulster, 2012). She was co-editor of an international collection of essays on socio-economic rights: 'Justiciability of Human Rights Law in Domestic Jurisdictions'' (Springer, 2015). She has served as an EU-funded country reporter (UK, NI) for the Asser Inst./Utrecht University on matters of cross-border family law, in 2008 and 2017, contributing to an EU-wide guide for family law practitioners (2018). She was a co-convenor of the International Society of Family Law's Regional Conference in Derry, N Ireland (2010). She was a trustee of Londonderry Inner City Trust from 2012 -2016, and has been a trustee for Kinship Care NI since 2014, and a board member for Apex Housing NI since 2013. She has served as an external examiner for a number of LLB and LLM programmes throughout the UK and Ireland, since 1999, “‘A Just War’ - Protecting Indigenous Cultural Property”, 2004, [http://classic.austlii.edu.au/au/journals/IndigLawB/2004/43.html]//pranav](http://classic.austlii.edu.au/au/journals/IndigLawB/2004/43.html%5d//pranav)

* Also implicates 2nr “everyone dies” discourse – criticizes ‘greater good’ discourse and means that that discourse just turns native populations into “haphazard aggregations”
* Neg is assimilationist policy

When indigenous cultural property rights are defined by western concepts of ‘property ownership’, they risk the fate of indigenous land rights. Where entire continents were lost under terra nullius, indigenous peoples’ descendants now face a ‘cultural genocide’ with ‘discovered’ culture appropriated to benefit the ‘greater good’. Human rights issues resurface; would cultural property rights be better protected via segregation or ‘integration’ into majority cultures? Should rights be framed as collective ‘group’ claims or as ‘matters for individuals’?[2] If so, might cultural property be capable of ‘self-determination’? If ‘cultural secession’ occurs, demands for defined territories become paramount. Human Rights lawyers may have to revise emerging customary norms given recent cases highlighting western judicial bias, where European definitions of ‘land use’ disregard the nomadic, ‘hunter-gatherer’ nature of many indigenous populations, Anglo-western preoccupation with ‘alienability’ conflicts with the ‘perpetual’ nature of indigenous ownership[3] and the ‘individualistic orientation of Anglophone countries’[4] ignores the communal, ‘caretaker’ nature of aboriginal ownership. Although Mabo[5] appeared to extinguish terra nullius, its legacy lingers on. This paper examines whether legal ‘blemishes of the past ... translate into current inequities’. The ‘evolving character’ of international jurisprudence initially sought to justify colonialism’s ‘brutal settlement patterns’.[7] Early defenders of aboriginal rights[8] highlighted the ‘essential humanity of the Indians’[9] and ‘condemned’ colonial abuses, but nevertheless made ‘integrationist assumption(s)’[10] that colonisation was ‘an incessant trend, heralding a new era of progress and prosperity’.[11] The concept of ‘noble primitive, close to nature’,[12] needing fiduciary protection to use property correctly, runs through nineteenth-century American jurisprudence[13] and treaties.[14] These ‘constrained claims and kinds of remedies’[15] displaced the ‘personal and cultural identity’[16] of native people, who were forced to ‘adopt a view of themselves ... that fits with the rights-conferring political machinery of the state’.[17] With cultural property rights, loss of identity is pronounced, and the consequences profound; ‘what was fluid, changeable and non-material, becomes ... a predictable objective of a colonial state.’[18] Just as land was state-ceded in return for rights to ‘reserve’ some of it, the ‘contrivance of sameness’[19] now seems necessary to protect cultural rights. Assimilationist government policies, despite ‘politically correct language of participation and citizenship,’[20] frequently ‘deny difference’; underlying colonialism ensures that native populations remain ‘haphazard aggregations’[21] rather than distinct, rights-bearing state ‘beneficiaries’.

#### The TRIPS agreement is *forged* in a biocolonial exclusion of indigenous communities through a false belief of indigenous peoples as merely holders. This is inextricably tied to global demand for medicine and MNCs surge in biopiracy.

**Breske 3** [Ashleigh, visiting assistant professor of international studies in the global politics and societies (GPS) department @ Hollins University. She earned her Ph.D. in planning, governance, and globalization at Virginia Tech, her M.A.L.S. in social sciences with a focus on Roman history from Hollins University, and her B.S. in biology with a concentration in classical studies and chemistry. Her current research explores how institutions and cultural values mediate changes in repatriation policy for indigenous cultural property, “Biocolonialism: Examining Biopiracy, Inequality, and Power”, Spectra, 6(2), pp.58–73. DOI: [http://doi.org/10.21061/spectra.v6i2.a.6]//pranav](http://doi.org/10.21061/spectra.v6i2.a.6%5d//pranav)

**The global demand for medicinal drugs has led to an increase in biopiracy in the Global South**. Once companies find something they believe will be profitable, they want to patent it straightaway so that no one else can capitalize off it. Patents are an easily accessible source of income for those able to apply for them. In fact, patents act as an exclusive control on a product, and, when corporations hold patents on biodiversity, they are creating a monopoly on food and health.xxviii In some ways **it is impossible for those in developing countries to compete with MNCs due to how patents and intellectual property rights are sustained**. Since patents are held nationally instead of internationally, most patent holders tend to be from more developed countries. Because of this divide, **it is possible to inflate the price of patented medicines so that corporations can make an even greater profit, which leads to more global inequalities.** **Rich states can also pay for access to technology for research and resources to control epidemics and infectious diseases more readily than poorer areas of the world.** **With the establishment of the World Trade Organization in 1994, international trade negotiations opened, and western notions of intellectual property rights took a firm hold in pharmaceutical research and development, increasing the strength of MNCs.** This was classified under TRIPS, the Agreement on Trade Related Intellectual Property Rights.xxix TRIPS was negotiated at the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) and set the standard for member states to recognize the same intellectual property rights. This then meant that industries could bypass local patent law by registering their patents in the most favorable jurisdiction.”xxx Before TRIPS, which set consistent requirements, intellectual property was considered a domestic issue with protections set on the national level. However, with TRIPS, transnational corporations are now much more successful at acquiring patents. xxxi For example, looking at the number of patents held at the end of the twentieth century, most were filed by the United States (41.8%) and Europe (41.95%).xxxii **The TRIPS agreements and domestic patent laws, specifically US law, shapes international IPRs and show that the legal system is excluding indigenous or marginalized communities**. xxxiii **There has been a push for TRIPS, predominantly by the pharmaceutical industry, to restrict profit potential by indigenous communities.** Corporations make minor genetic or chemical formula changes for their intellectual property claims and patents and can then claim their product is no longer directly linked to the initial source. Debra Harry has claimed that **the main problem with biocolonialism is the “manipulation and ownership of life itself, and the ancient knowledge systems held by Indigenous peoples.”** xxxiv **The problem stems from the belief that indigenous peoples are merely the holders, not owners, of communal knowledge. What are not considered are their territorial rights to the resources on their lands**. Xxxv

#### Plan: The member nations of the World Trade Organization should eliminate patents on medicines based on Indigenous knowledge from patentability.

**IPW ‘06** [Intellectual Property Watch quoting Debra Harry -- executive director of the Indigenous Peoples’ Council on Biocolonialism, and a member of the Paiute tribe in the United States, “Inside Views: Indigenous Groups Tell WIPO, ‘Don’t Patent Our Traditional Knowledge’”, [https://www.ip-watch.org/2006/12/06/inside-views-indigenous-groups-tell-wipo-dont-patent-our-traditional-knowledge/]//pranav](https://www.ip-watch.org/2006/12/06/inside-views-indigenous-groups-tell-wipo-dont-patent-our-traditional-knowledge/%5d//pranav)

* Examples of medicines the plan would affect include reserpine, digitoxin, American ginseng medicines, Qualaquin, Neem, Turmeric, Aspirin, taxol, Ayurvedic medicines, etoposide phosphate
* The ev cites an actual joint statement from a tribal group
* Ev also answers the “what if a company decides to j mass produce” question

The joint statement of tribal group says: “**Any attempt to develop IPR-based mechanisms to ‘protect’ IK [indigenous knowledge] actually poses much more threat to our knowledge, as a whole, than it can ever claim to prevent**. **Rather than protect, the imposition of IPRs over IK actually would serve to facilitate the alienation, misappropriation, and commercialization of IK.”** “We believe patent applications that include or are based on IK should be specifically excluded from patentability. **In IP terms, we’re sure you understand that these patent claims would fail to meet the test of innovation, novelty or inventiveness**. But more importantly for Indigenous peoples, **such patent claims should be denied because IK is in the Indigenous domain; that is, it is already under the jurisdiction of Indigenous legal systems, which protect the IK in perpetuity as the inherent and inalienable cultural property of Indigenous peoples.**

#### This invalidates the IPRs of western pharmaceutical companies and *terminates* their ‘*ethical right’* to Indigenous knowledge.

**Breske 4** [Ashleigh, visiting assistant professor of international studies in the global politics and societies (GPS) department @ Hollins University. She earned her Ph.D. in planning, governance, and globalization at Virginia Tech, her M.A.L.S. in social sciences with a focus on Roman history from Hollins University, and her B.S. in biology with a concentration in classical studies and chemistry. Her current research explores how institutions and cultural values mediate changes in repatriation policy for indigenous cultural property, “Biocolonialism: Examining Biopiracy, Inequality, and Power”, Spectra, 6(2), pp.58–73. DOI: http://doi.org/10.21061/spectra.v6i2.a.6]//pranav

Looking at the production of pharmaceuticals, **we can see the importance of Intellectual Property Rights (IPRs) in the debate over the accessibility of indigenous knowledge to outside corporations and investors**. IPRs impact many different fields: healthcare, biodiversity, technology, human and cultural rights, research and development, and agricultural innovations; but, the international system that established international intellectual property rights was hastily organized and linked to trade agreements. xli Shiva claims **IPR laws, under the development of TRIPS and the World Trade Organization (WTO), “have unleashed an epidemic of the piracy of nature’s creativity and millennia of indigenous innovation**.” xlii Transnational corporations are taking advantage of slight “innovations” on traditional knowledge to maintain many of their IPRs. xliii **Together, IPRs and TRIPS, work to suppress indigenous peoples’ ability to control their traditional way of life**. The regulatory system includes domestic laws of developed areas of the world, like the United States, Japan, and Europe, and broader international intellectual property rights agreements. **These agreements resemble doctrines promoting colonialism since they are legal documents fostering the idea of ownership by the dominant colonizers.** Xliv Attempts have been made to establish a declaration that would negate corporate intellectual property rights if public health issues were brought forward by struggling nations’ governments. xlv **But this does not address the issue of restoring indigenous intellectual property rights. Large pharmaceutical corporations in the United States and the European Union have used their vast corporate wealth to prevent the nullification of their IPRs. The inability to invalidate their IPRs means that pharmaceutical companies have ensured rigidity in the trade agreements and prevented generics from being manufactured. This has also ensured their continued legal right to Indigenous knowledge, if not an ethical right**. xlvi Patents are an apparatus of power with universal political and social consequences. Patent policies are developed in western countries but affect poorer, marginalized areas of the world. Unfortunately, there is no international governing body through which all patents are channeled, and they are granted according to individual national domestic laws. These patents are generally established in western countries like Canada, the European Union, and the United States. For all intents and purposes, pharmaceutical companies have more legal rights than people due to trade liberalization.

#### Compensation tactics fail – they take too long and don’t end up benefitting Indigenous peoples.

**McGonigle ’16** [Ian Vincent, Assistant Professor of Global Science, Technology, & Society at Nanyang Technological University. Was previously a PhD Candidate in Anthropology and Middle East Studies at the Center for Middle Eastern Studies at Harvard University. He has published over a dozen original research articles in top academic journals, such as: Ethnos: Journal of Anthropology; the Journal of Law and the Biosciences (including the most-read article, with over 30,000 reads); Anthropology Today (cover feature); Journal of Neuroscience; Biophysical Journal; ACS Chemical Neuroscience; and Biochemistry., “Patenting nature or protecting culture? Ethnopharmacology and indigenous intellectual property rights”, Journal of Law and the Biosciences, Volume 3, Issue 1, April 2016, Pages 217–226, DOI: https://doi.org/10.1093/jlb/lsw003]//pranav

Previously, companies tended to compensate indigenous people for their role in the drug discovery process by according them a share of the profits from the drug once it had been commercialized. 6 **But the long period of time needed for drug discovery and clinical trials, often ten years or more, was thought to render such a mechanism of reciprocity unsatisfactory for the contemporary holders of traditional ecological knowledge (TEK)7 that help develop the drug**.8 Furthermore, **in most cases, the knowledge shared would not lead to a commercial end product, so that when compensation was structured in this way, no benefit of any kind would ultimately accrue to the indigenous people.**9

#### The role of the judge is to vote for the debater that endorses the best form of epistemic subsidiarity.

**McGonigle 2** [Ian Vincent, Assistant Professor of Global Science, Technology, & Society at Nanyang Technological University. Was previously a PhD Candidate in Anthropology and Middle East Studies at the Center for Middle Eastern Studies at Harvard University. He has published over a dozen original research articles in top academic journals, such as: Ethnos: Journal of Anthropology; the Journal of Law and the Biosciences (including the most-read article, with over 30,000 reads); Anthropology Today (cover feature); Journal of Neuroscience; Biophysical Journal; ACS Chemical Neuroscience; and Biochemistry., “Patenting nature or protecting culture? Ethnopharmacology and indigenous intellectual property rights”, Journal of Law and the Biosciences, Volume 3, Issue 1, April 2016, Pages 217–226, DOI: [https://doi.org/10.1093/jlb/lsw003]//pranav](https://doi.org/10.1093/jlb/lsw003%5d//pranav)

* TEK = Traditional Ecological Knowledge
* Sui generis j means like specific to them/ is latin for “their own”
* Epistemic subsidiarity is a legal framework for resolving ontological disputes in relation to varying definitions of nature this is a formalized legal strategy that can take place in multiple ways, but has the end goal of protecting spaces for the expression of local autonomy and legitimizing Indigenous processes – this does not entail leaving traditional policy spaces, but rather explains how to improve them and include Indigenous POVs into future action
* The framework is consequentialist (obviously limited as to what consequences matter), but is focused on producing the best legal strategy – if you prove that the squo/cp/alt or whatever is a better legal strategy for establishing protections for Indigenous populations or sui generis than the 1ac, you’d win – basic competition stuff lol
* To clarify, the 1AC does operate under a comparative worlds paradigm.

In response to these shortcomings, emerging insights from social studies of science may also help in thinking about the ethical problems, legal structures, and cultural clashes that anthropologists engaging in ethnopharmacology research may face. **Such scholarship may also offer insight for informing policy solutions and establishing better exchange agreements**. Jasanoff,61 for example, **has theorized a legal framework for resolving ontological disputes in relation to varying definitions of nature**. In a discussion of transnational risk governance, **she develops the idiom of ‘epistemic subsidiarity’ to describe a formalized legal strategy that could pave the way to ‘to protect spaces for the expression of local values and local autonomy’, and therefore also protect the legitimacy of local modes of reasoning, within the same judicial system.** ‘Epistemic subsidiarity’ is particularly salient to cross-border disputes where cosmopolitan exchanges require a formal system of reciprocity, compromise, and mutual respect of each party’s respective regimes of knowledge and value. For ethnopharmacology, implementing ‘epistemic subsidiarity’ might mean the establishment of special courts that would consider indigenous claims on their own terms. With the expert mediation by anthropologists, cultural diplomats, or leaders from different parties who can mediate between secular technoscience and indigenous culture, such courts could be a space where indigenous definitions of nature and property are heard in parallel to the interests of other parties, be they states, companies, or researchers. Further, **special laws could be written that would extend the protection of indigenous intellectual property to include non-modern understandings, including ambiguous spirit entities, or acquired TEK.** A system of epistemic subsidiarity also requires political decisions be made at the ‘lowest feasible level of governance’ so that local values and concerns are first taken into account.62 **With epistemic subsidiarity, different knowledge regimes can exist side by side (such as, for example, biology, international law, state law, and local indigenous law and healing practices), without one necessarily subordinating to another**. **Epistemic subsidiarity could also facilitate the writing of trade agreements on local indigenous terms, while also recognizing international law and other parties’ interests. Combining epistemic subsidiarity with the emerging anthropological perspectives that regard indigenous visions of their world with parallel ontological status to Western science could deliver ‘symmetry’ in the negotiation of trade agreements, and consequently, could help resolve the ethical dilemmas of ethnopharmacologists and indigenous peoples.** Stories like that of the Mexican peasants and their redundancy from the industry due to shortcuts made by chemistry in conjunction with IPR, or indeed the recent case of the Peruvian people who helped Napo develop ‘Dragon’s blood,’ show that IPR are not adequate instruments for representing or protecting indigenous TEK and their embodied know-how. Moreover, **current laws do not afford equal status to, or demand a symmetrical engagement with, non-modern cultural values and ambiguous local entities**. Further, **most discourse within the ethnopharmacology community is oriented to the biological and pharmacological sciences, with much less attention paid to the broader social, political, and anthropological dimensions of the research**.63 Consequently, the ethnopharmacology community has not yet addressed these questions with sustained debate, nor has there been much done to envision an ethical platform upon which to establish exchange agreements that incorporate ‘non-modern’ visions of the world. **Indigenous communities therefore need sui generis laws to protect their shared cultural heritage and shared natural resources**. So far, ‘Brazil, Costa Rica, India, Peru, Panama, the Philippines, Portugal, Thailand and the USA have all adopted sui generis laws that protect at least some aspects of traditional knowledge’.64 But **extending the concepts of ontological pluralism and epistemic subsidiarity into indigenous IPR laws could help lawmakers resolve the ethical and legal dilemmas over whose knowledge, and definitions of property, should prevail in exchange agreements and legal disputes.**

#### The logics of settler colonialism *have not* disappeared, but merely *reformulated* extinction discourse to justify the *biocolonial exploitation* of natural resources and Indigenous knowledge in the west’s “global resource frontier” through narratives of inevitable Indigenous extinction.

**Barker ’19** [Clare, Associate Professor in English Literature at the University of Leeds and their research focuses on postcolonial literatures and cultures, and it engages centrally with disability studies and medical humanities, “Biocolonial Fictions: Medical Ethics and New Extinction Discourse in Contemporary Biopiracy Narratives”, 2019, 19(2): 94–109, [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7116577/]//pranav](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7116577/%5d//pranav)

**The logic of biocolonial extractivism operates through a reorientation of the temporal formations of settler colonialism, which equate settler practices with development and consign Indigenous peoples to the past.** **The land dispossessions of the colonial era were facilitated by powerful narratives of inevitable Indigenous extinction:** ‘vanishing Indians’, Maori and Aboriginal ‘dying races’. As critics have shown, **contemporary biocolonialist initiatives operate on similar assumptions, under which indigenous biospecimens must be preserved and biological data acquired before they vanish forever**. Joanna Radin demonstrates that, since the mid-twentieth century, the ability to freeze and store blood and other organic samples has ‘emerged as a potentially powerful strategy for preserving fragments of a world that appeared to be increasingly in flux’. It enables ‘biological material to be studied in the present and especially in the future’, when (whether due to genetic admixture, European diseases, or environmental damage produced by the industrialized global North) ‘the individuals from whom it had been extracted were expected to have disappeared or changed beyond recognition’.3 In this article, I **explore the intertwined relationship between medical research ethics and the logic and ideology of biocolonialism** as it is represented in two contemporary American novels, Ann Patchett’s State of Wonder (2011) and Hanya Yanagihara’s The People in the Trees (2013). These novels depict ‘medical adventurer[s]’4 undertaking biocolonialist excursions into the remote jungles of, respectively, the Amazon and the Pacific, and are centrally concerned with the methods and infrastructure of biomedical and pharmaceutical research. In both cases, the fictional **scientists’ ethically problematic research practices implicate** **them in** what Pauline Wakeford calls ‘**two entangled narratives of death and disappearance: the grand récits of wildlife extinction and the vanishing Indian’.**5 **I focus in particular on how these texts, by presenting us with fictional bioethical quandaries related to human longevity and reproduction, engage with the new formulations of extinction discourse produced by the life sciences**. Patrick Brantlinger asserts that **colonial ‘extinction discourse was performative in the sense that it acted on the world as well as described it’**.6 State of Wonder and The People in the Trees **both imagine biological discoveries with the potential to extend human lifecycles, but these research endeavours are steeped in extinctionist ideology and themselves set in motion the decimation of previously thriving Indigenous communities**. **Aspirational narratives of ‘eternal life’ (in Yanagihara) and ‘world health’ (in Patchett) are underpinned by the knowledge that these communities, reframed as research subjects, are likely to vanish in the wake of what Warwick Anderson calls ‘scientific colonialism’, along with their unique ecosystems.**7 The different narrative temporalities of these texts – Patchett’s anticipating a significant breakthrough in global health, Yanagihara’s narrated retrospectively from a position of irreversible loss – produce divergent valuations of human and nonhuman lives and different perspectives on the ethics of biopiracy, as I shall discuss. But in reading them together, I demonstrate how fictional engagements with biocolonial science illuminate the continuities between colonial-era extractivism and contemporary research practices. **In their temporal reorientations and their ability to imagine actual and potential acts of extinction, these texts resituate extinction discourse squarely within the context of twentieth- and twenty-first-century bioscientific experimentation**. State of Wonder follows Marina Singh, a pharmacologist for a multinational pharmaceutical corporation, Vogel, on her expedition into the Amazon to investigate the death in the field of her colleague, Anders Eckman, and to assess the progress of a senior scientist, Annick Swenson, who is developing a fertility drug for Vogel while living with a remote tribe, the Lakashi. Swenson has discovered that the Lakashi women’s practice of chewing bark from a particular local tree (the Martin tree) not only alters their reproductive chemistry, allowing them to conceive and give birth into their seventies and eighties, but also inoculates them against malaria. Alongside their work on the fertility drug, Swenson and her team are surreptitiously developing a malaria vaccine at Vogel’s expense, which will have little appeal to company shareholders even though it ‘will have enormous benefits to world health’, since ‘[t]he people who need a malarial vaccine will never have the means to pay for it’.8 **As the narrative unfolds, the protection of the Lakashi, their lifeways, and their environment is pitted against this urgent global health imperative to save the lives of the ‘[e]ight hundred thousand children’ who, as Swenson tells Marina, ‘die every year of malaria’ in the so-called ‘Third World’.9** The People in the Trees is framed as the memoirs of Norton Perina, a ‘renowned immunologist’ who, as a young doctor in 1950, joins an anthropological expedition to U’ivu, a fictional Micronesian state.10 Along with his anthropologist colleagues, he ‘discovers’ a ‘lost tribe’ living on the island of Ivu’ivu whose ritual ingestion of a sacred turtle endemic to the island, the opa’ivu’eke, causes extended longevity, with some tribe members apparently living for several hundred years. Perina’s research on this phenomenon earns him a Nobel Prize for Medicine, but also kickstarts a rapid process of biocolonial incursion on this island that has ‘never [before] been colonized’, beginning with pharmaceutical companies, seeking to develop ‘age-retarding drugs, … anti-aging skin creams, [and] elixirs to restore male potency’, ‘swarming throughout Ivu’ivu on the hunt for the opa’ivu’eke’.11 It results in the extinction of the turtle, the razing of the island, and the decimation of the Ivu’ivuan community through an accelerated experience of the impacts of colonization, including forced displacement, alcoholism, and disease. Both texts emphasize the overdetermination of their respective jungle environments by longstanding colonialist tropes of exotic difference that are inflected by bioscientific discourse. **The Pacific island, as Elizabeth DeLoughrey has demonstrated, has long been figured as a remote, ‘hermetically sealed laboratory’, ‘deemed ahistorical and isolated’ from modernity and therefore ideal for experimentation in anthropology, ecology, and nuclear science**.12 The Amazon, meanwhile, is imagined as what Veronica Davidov terms a ‘pharmacopia’ that holds within its rich ecosystems ‘fantastic cures for illnesses that defy the capacities of the Western pharmaceutical industry’, or, as Dr Swenson puts it in State of Wonder, ‘some sort of magical medicine chest’.13 **Under the globalized conditions of the biomedical and pharmaceutical industries, the jungle spaces outside the West are vulnerable to exploitation due to their construction as ‘global commons’ or ‘global resource frontier[s]’ available to be harvested for their medical riches**.14 As Swenson asserts in an unapologetic utilization of extractivist rhetoric: ‘there is much to be taken from the jungle’.15 Through their focus on the activities of life scientists in the interconnected fields of big pharma and global health, both novels appear to offer a critique of the impacts of biocolonialism on Indigenous people and the ecosystems in which they exist. But, as I will show, Perina’s retrospective narration in The People in the Trees brings into critical focus the extinctionist logic of biocolonial science, while State of Wonder’s anticipatory positioning is ultimately bound up with the future-oriented rhetoric used to justify much exploitative and damaging scientific research. The People in the Trees introduces its Ivu’ivuan ‘lost tribe’ through the lens of 1950s anthropology. As an ambitious junior doctor on an anthropological expedition, Perina observes his anthropologist colleagues with a degree of scorn regarding their research activities, which seem to consist of conducting ‘fruitless interviews with the dreamers’ – the elderly Ivu’ivuans who have ingested opa’ivu’eke flesh and who are consequently aged between one and three hundred years old – and ‘filling entire notebooks with minute descriptions of the most mundane of activities’.16 The text enacts a forensic examination of anthropological method and ideology, presenting us with anthropologists who are, in line with recent critiques of the discipline, ‘entrenched in island boundedness, isolation, and atemporality’ in this period before the field’s critical turn.17 In thematizing this mid-twentieth-century anthropological perspective on the Indigenous tribe, Yanagihara draws attention to anthropology’s foundational role in establishing problematic research engagements with Indigenous people. **The ‘funereal but very modern science of anthropology’, as Brantlinger terms it, was heavily implicated in, and dependent upon, extinction discourse ‘in its attempt to learn as much as possible about primitive societies and cultures before they vanish forever’**.18 The People in the Trees dramatizes what Johannes Fabian famously termed ‘**the denial of coevalness’ – the assumption that supposedly ‘primitive’ Indigenous subjects of anthropological study exist on a different temporal plane from the ‘modern’ scientists studying them**.19 Yanagihara employs contrasting notions of time in Perina’s account of the villagers and the scientists. The researchers obey a ‘definition of time … determined in the part of the world where people consulted clocks and made and kept appointments’ (consonant with Mark Rifkin’s notion of ‘settler time’), while in the Ivu’ivuan jungle, Perina recounts, ‘time twirled itself into long, spiraling whorls, defying biology and evolution; not even the human body respected it’.20 He understands the villagers to possess ‘no notion of time, no notion of history’, despite being aware of their 400-day year and system for measuring birthdays.21 **While extinction discourse in the colonial era was mobilized to make way for the settler, conveniently bypassing Indigenous sovereignty on the land with the assumption of their inevitable elimination, in this context of 1950s Pacific anthropology, the denial of coevalness makes way for biocolonial exploitation of natural resources and Indigenous knowledge.** The research of the lead anthropologist, Paul Tallent, on a U’ivuan origin story linking the opa’ivu’eke to immortality, as well as on recent island histories rich in ecological and climatic knowledge, forms the basis for Perina’s biomedical experimentation on the dreamers and turtles.

#### Research paradigms are not static, but rather in a *constant fluidity* that mandates the deployment of mixed methods to create effective change. The 1AC is NOT western pragmatism, but a *radical and unsettling form* of decolonizing research practices as the starting point for the broader project of decolonization.

**Held ’19** [Mirjam, PhD student @ Dalhousie University, “Decolonizing Research Paradigms in the Context of Settler Colonialism: An Unsettling, Mutual, and Collaborative Effort”, 01-23-2019, International Journal of Qualitative Methods, DOI:10.1177/1609406918821574]//pranav

**Because paradigms are fluid scholarly constructs that are not homogenously applicable to the entire research community**. In his seminal work, The Structure of Scientific Revolutions, Kuhn (1962) defined paradigms “to be universally recognized scientific achievements that for a time provide model problems and solutions to a community of practitioners” (p. x). Thus, **a paradigm is nothing static** nor is it applicable to any and all researchers. According to Kuhn’s original definition, **a paradigm can either change over time or fall out of fashion**. Further, it provides guidance about which questions to ask and how to answer them only to a smaller subset of researchers, namely a scholarly community that works from the same theoretical and empirical background (Kuhn, 1996, as cited in Morgan, 2007). Or as Morgan (2007) put it, paradigms can be seen “as shared beliefs among members of a specialty area” (p. 53). While this view was first put forward for Kuhn’s linear paradigm shift model in which a new paradigm replaces and older one, it is equally applicable to the proliferation perspective. Thought and theories that were to be developed into nonpositivist research paradigms for qualitative social inquiry emerged in the 1960s and 1970s (Denzin & Lincoln, 1994, 2000, 2005). While the development of the postpositivist, constructivist and what is now often called the transformative paradigm was characterized by a number of defining crises (Denzin & Lincoln, 1994, 2000, 2005), the emergence of mixed methods, specifically the combining of quantitative and qualitative methods, led to confrontations that are now known as “paradigm wars” (Denzin, 2010; Teddlie & Tashakkori, 2003). Researchers have employed mixed methods since the early days of qualitative inquiry in the 1900s, but explicit multimethod research designs did not emerge until the 1960s (Teddlie & Tashakkori, 2003). In the 1980s, mixed methods that combined quantitative and qualitative methods seemingly had no place in methodological scholarship as their respective paradigms, that is, postpositivism and constructivism, were deemed incompatible (Denzin, 2010). **Then, some scholars of this specialty area took their shared conviction, namely that they should have the freedom to choose whatever method or combination of methods is most appropriate for answering the research question, and created the pragmatic paradigm** (for a more detailed account of the history of mixed methods, see Denzin, 2010; Teddlie & Tashakkori, 2003). **This pragmatic move allowed them to combine methods and thus methodologies that were previously (and still, by some scholars) believed to be irreconcilable**. From a paradigm incompatibility perspective, merging Western and Indigenous methodologies is equally impossible. Can the pragmatic paradigm thus provide a framework under which transformative and Indigenous methodologies can be used in combination? Not directly. The pragmatic paradigm was constructed to provide the flexibility to make quantitative/qualitative mixed-methods research legitimate from a philosophical/theoretical point of view. Early pragmatism (in the late 19th and early 20th centuries) was a philosophical movement that emphasized research as a social endeavor (Maxcy, 2003). Today, issues of power are still important to researchers who practice mixed-methods research in the context of feminist approaches (e.g., Hesse-Biber, 2010; Hesse-Biber & Griffin, 2015) or to generally challenge dominant views of reality (e.g., Hesse-Biber, 2010; Mertens, Bledsoe, Sullivan, & Wilson, 2010). Yet often, current practices of mixed-methods research under the pragmatic paradigm lack a true axiological stance, either overlooking or ignoring questions of ethics or value (Biddle & Schafft, 2015, p. 323; Teddlie & Tashakkori, 2009; p. 90). Research, however, is always already political (Denzin & Lincoln, 2008b, p. xi) and thus any paradigm that guides transformative/Indigenous research—which is inherently emancipatory/liberatory—needs to include values and let them play a formative role. Still, **the creation of the pragmatic paradigm can provide a model for rejecting the “either-or” of two seemingly incommensurable paradigms.** The transformative paradigm is based on a Western worldview, while Indigenous paradigms are rooted in a holistic, localized worldview. Nevertheless, they share many of their philosophical underpinnings. Another common tenet are decolonizing aspirations. These, however, are more than just another social justice issue. Decolonization is, by default, an unsettling enterprise and therefore “cannot easily be grafted onto pre-existing discourses/frameworks” as stated by Tuck and Yang (2012, p. 3). In the Canadian context of settler colonialism, decolonization is about land, resources, sovereignty, and self-determination (Tuck & Yang, 2012); as such, it involves the creation of a new social order. Thus, it is a mutual undertaking involving the colonizer and the colonized (Beeman-Cadwallader, Quigley, & Yazzie-Mintz, 2011). **I suggest applying this radical interpretation of decolonization to the decolonization of research in order to advance the discussion on multiparadigmatic research spaces.** **Radically decolonizing research means that any decolonizing research paradigm must be developed conjointly between Western and Indigenous researchers, creating a new research framework altogether**. It also means that decolonizing paradigms is not a means to an end (e.g., to provide alternative pathways to research or to make the research endeavor more inclusive and diverse), but just a small piece in the puzzle that is the decolonization project, which is ultimately a radical social reform. Decolonizing research under these premises will be an unsettling collaboration with fraught solidarity (Tuck & Yang, 2012) and an unknown outcome. **Decolonization is a long-term process involving the bureaucratic, cultural, linguistic, and psychological divesting of colonial power** (Smith, 2012) **by undoing “the privileging of dominant Euro-centred cultural values and beliefs in education, scholarship, knowledge production, the legitimization of intellectual capital, and the networks and systems of power”** (Styres, 2017, p. 19). **It is about reinventing the coexistence of the currently dominant society, more recent settlers and the Indigenous peoples by redefining where power is located.** This shift will include allowing the colonized to view and understand themselves through their own worldviews (Chilisa, 2012, p. 13). There is a progression to this process. Based on the experiences in his native Hawaii, Laenui (2000) identified five stages of the decolonization process: rediscovery and recovery, mourning, dreaming, commitment, and action. These phases share overlaps, and can happen at the same time and in various combinations (Laenui, 2000). Laenui’s phases were formulated for Indigenous or other colonized peoples; however, the decolonization of the dominant society will similarly proceed in stages. With dominance comes privilege; in order to undo white privilege, we need to thoroughly understand it (Land, 2015, p. 31). Thus, for the colonizer, too, the action phase will have to be preceded by a clear comprehension of the past and the status quo, before the hegemonic concept of European/Western thought can be challenged and a more equitable and collaborative future envisioned and attempted. The notion that “there are no spaces that are not colonized” (Anderson, 2004, p. 239) reinforces the need for decolonization to be an all-encompassing and collaborative effort. **It does not mean, however, that the perpetrators and the victims play the same role;** the burden is with the dominant society who has to take responsibility for its actions (see Getty, 2010, p. 7; Tuck & Yang, 2012, p. 35). Societal structures are either colonizing or liberatory. The shift from the former to the latter will be an unsettling and challenging process that, at best, will lead to mutual understanding, healing, and, ultimately, a postcolonial coexistence and collaboration. I interpret this postcolonial future as an era when the current ongoing oppression and marginalization of Indigenous peoples (collectively and individually) as a result of colonialism has been redressed and the former colonizer and the formerly colonized have found a balance that honors the Treaty rights, Aboriginal rights, and the individual and collective rights of Indigenous peoples as enshrined in the UNDRIP. The Canadian government is committed to acting upon the calls to action put forward by the TRC (Trudeau, 2015) and has indeed recently become a full signatory of the UNDRIP (Government of Canada, 2016). But when it comes to implementing deeds that advance reconciliation and decolonization on the ground, there has so far been much more talk than walk. While a change in rhetoric around Canada’s colonial past and neocolonial present is a start, only the implementation of the demands for—and rights to—indigenization, self-determination, and equality will lead to real change. This postcolonial prospect as envisioned by decolonization is not to be confused with the term postcolonialism that is currently in use in academia. Influenced by postmodernism and poststructuralism (Anderson, 2004), postcolonialism or postcolonial theory is “a critical theory that provides a way of deconstructing colonialism and its historical effects on the colonized,” as summarized by Getty (2010, p. 7). Helping to reveal the unequal power relations of past and present colonialism, postcolonial theory has been used by non-Indigenous scholars to analyze and critique the impacts of colonialism (Browne, Smye, & Varcoe, 2005). However, the approach is rather descriptive and does not reflect Indigenous ways of knowing (Getty, 2010); thus, Indigenous scholars have criticized its failure to support decolonization and Indigenous self-determination (e.g., Grande, 2000; Kovach, 2010; Smith, 2012). Decolonizing approaches, on the other hand, are not satisfied with describing and critiquing unequal power relations stemming from colonialism, they strive to undo them. In terms of decolonizing methodologies, Indigenous scholars made the first step by reviving, articulating, and using Indigenous methodologies and research paradigms for their research (e.g., Bishop, 2005; Graveline, 2000; Hart, 2010; Kovach, 2009; Rigney, 1999; Wilson, 2008). Based on local and relational worldviews, these paradigms, however, are only accessible to the respective Indigenous communities. Non-Indigenous scholars who support the self-determination of Indigenous peoples—also referred to as allied others—then tried to incorporate Indigenous ways of knowing and knowledge production into their research but still worked from a Western paradigm (e.g., Jackson-Barrett et al., 2015; Mertens, 2012). Many scholars engaged in research that tries to bridge Western and Indigenous approaches have expressed frustration over the fact that the ethical space of such research is ill-defined. Particularly, graduate student researchers (both Indigenous students and allies) who wish to embark on decolonizing research have to stem a lack of guidance and understanding, be it from advisory committees, ethics boards, university legal services, or granting agencies which are still often biased toward Western research approaches (cf. Kovach, 2009; Kuokkanen, 2007; Simonds & Christopher, 2013; Snow, 2018; Styres, Zinga, Bennett, & Bomberry, 2010). Both allies and Indigenous scholars are in search of a research ethics that is feminist, caring, communitarian, holistic, respectful, mutual (i.e., power balanced), sacred, and ecologically sound (Lincoln & Denzin, 2008, p. 569). In this quest, **an increasing number of authors has developed thought around a new multiparadigmatic space that combines elements of the transformative and of an Indigenous paradigm.** Indigenous scholars from around the world have put forward indigenized paradigms that are based on Indigenous perspectives and philosophical assumptions: examples are the Kaupapa Māori research approach (e.g., Bishop, 2005; Mane, 2009; Smith, 2000), Rigney’s (1999) Indigenist research paradigm for Australian Indigenous peoples, research frameworks developed by North American Indigenous peoples (e.g., Graveline, 2000; Hart, 2010; Kovach, 2009; Wilson, 2008) and by African scholars such as Chilisa’s (2012; Chilisa et al., 2017) postcolonial Indigenous research paradigm and Afrikology as a transdisciplinary approach (Buntu, 2013; Nabudere, 2011, 2012). Another transdisciplinary pathway is two-eyed seeing, coined by Mi’kmaq Elder Albert Marshall and first developed as a colearning journey that weaves together Indigenous and Western knowledges in science education (Bartlett, Marshall, & Marshall, 2012).2 These Indigenous paradigms can be used by Indigenous and non-Indigenous researchers alike, for, as Chilisa et al. (2017) posit, **paradigmatic positions need not be treated in exclusivist terms, that is, that the use of one precludes thinking in terms of the other.** Recognizing the need for diversity among the current “big four” (Dillard, 2006) Western research paradigms (postpositivist, constructivist, transformative, and pragmatic), Indigenous and Western scholars have called for the inclusion of a fifth paradigm, one based on non-Western perspectives, be they African, Eastern, African American, or Cree (e.g., Buntu, 2013; Chilisa, 2012; Chilisa et al., 2017; Dillard, 2006; Romm, 2015; Russon, 2008; Wilson, 2008).

#### *Progress* for Indigenous peoples is slow, but history proves it *is* *possible* – every small change matters.

Ecohawk & Drew ’20 [John Ecohawk is executive director of the Boulder, Colorado-based Native American Rights Fund and is a member of the Pawnee people, Kevin Drew is the assistant managing editor for international news, “Native Americans' Slow Path to Progress”, 07-15-2020, https://www.usnews.com/news/best-countries/articles/2020-07-15/supreme-court-ruling-puts-focus-on-slow-path-to-progress-for-native-americans]//pranav

In an age of growing global protests against racial inequalities, last week's U.S. Supreme Court decision to classify about half of Oklahoma as a Native American reservation put a spotlight on the economic, health and educational disparities that countries' indigenous peoples still face around the world. A 2009 U.N. report, for example, chronicled the widespread poverty, unhealthy living conditions and food insecurity that indigenous peoples face in the United States, Canada, Latin America, Australia, New Zealand and throughout Asia. A decade later, however, little progress has been made. A World Bank report published at the end of 2019 notes that the 476 million indigenous peoples in 90 countries make up about 6% of the global population, but account for 15% of the world's extreme poor. In Canada, a June 2019 government report stated that the deaths of thousands of indigenous women in recent decades constituted genocide and was the result of discrimination and the government's failure to protect First Nations people. And last February, Australian Prime Minister Scott Morrison conceded that his country's national policies to improve indigenous inequalities had failed and needed to be replaced. Those inequalities, including restricted access to national health care systems, make indigenous communities around the world especially vulnerable to the impacts of natural disasters and disease outbreaks such as the current COVID-19 pandemic, the World Bank report said. Still, this may be a pivotal time for activists pushing back against systemic racism against Native Americans. The Supreme Court's 5-4 ruling on July 9 decided whether lands of the Muscogee (Creek) Nation remained a reservation after Oklahoma became a state. The decision came days after a federal judge ordered the Dakota Access pipeline to be shut down, a major victory for Native American communities that raised environmental concerns the pipeline posed to tribal lands. And on Monday, Washington, D.C.'s NFL team announced it would change its nickname, a move activists have sought for decades to eliminate the team's use of the racial slur. U.S. News & World Report spoke with John Echohawk, executive director of the Boulder, Colorado-based Native American Rights Fund. The 74-year-old Echohawk, a Pawnee, co-founded the NARF in 1970 after becoming one of the first U.S. citizens to graduate with a law degree focused on Native American law. Today, NARF also has offices in Washington, D.C., and Anchorage, Alaska, has a staff of 35 employees, including 18 ½ full-time attorneys operating on a $12 million annual budget. Echohawk discussed the significance of the Supreme Court's Oklahoma ruling, and the slow, sometimes tortured path to progress for Native Americans. Can you put into historical context how significant the July 9 Supreme Court ruling concerning Oklahoma is for Native American rights? The Creek Nation treaty was the first one (signed with the U.S. government) so this has been an issue going on and on for all these years. The question is, what's the reservation's boundaries? Is it still intact? Has it been set in treaties or has it been changed by Congress? The Supreme Court answered that – a treaty is a treaty. It stays in effect until Congress changes it with explicit language. That never happened, so the boundaries are still intact. Do you anticipate the ruling having a spillover effect across the country? With 564 tribes across the country, there are plenty of disputes about boundaries and jurisdictions. So this (the Supreme Court ruling) is another legal precedent that talks about the clear rules you would use to analyze whether a boundary has been diminished or not. There are probably some cases out there that benefit from this clarification. What type of cases does your organization typically focus on? We have an all-native board of directors and there's no way we can undertake to represent all of the tribes, organizations and individuals that call us needing representation, so we have to be very selective and strategic. Our board has set up some priorities for us to follow. There are five and they're on our website: protection of tribal existence; protection of our tribal natural resources; protection of our human rights; holding the government accountable to the treaties and laws they passed to benefit us; and fifth, develop Indian law and educate the public about Native American law and policy. Can you discuss the development of the federal government's Native American policies? That basically requires a history lesson and it starts with 1492 and the first contact (between Europeans and native tribes). The European nations eventually came to realize tribes are nations, so they started resolving these issues through treaties. This practice found its way into the U.S. Constitution in 1787, and Congress was given the authority in Article I to deal with various sovereigns, foreign nations, the states and the tribal nations. And so we started entering into treaties … hundreds of treaties. Those treaties had resolved plenty of conflicts and land issues. But in 1871 the U.S. House of Representatives became jealous of the U.S. Senate because they were the ones conducting Indian affairs – the treaties could only be changed by the Senate. So Congress passed a law saying from now on we're going to deal with tribes through federal law. Federal Indian law and policy began developing in the 1880s and Congress thought it was wise to start assimilating and breaking up tribes and making them live like white people. One of the main ways they did that was to do what they call "allotment" … to take the tribal nations and reservations and take that land and divide it up and give individual tribal members the parcels of lands – allotments. What they didn't give to individual tribal members they would open up for settlement by non-Indians to come onto those reservations and buy that land and live among the Indians. Over the years this patchwork land ownership pattern was called checkerboard reservations. This didn't happen to all of the tribes, it happened to some of the tribes and one of them was the Creek Nation. The tribes lost about two-thirds of their lands through that process, and basically the tribes became destitute. That takes us into the 20th century. How did U.S. federal policy for Native Americans change? After the Great Depression the U.S. (government) realized that allotment policy was a mistake and so they stopped it and passed the Indian Reorganization Act, which started recognizing tribal governments and the right of tribal governments to run tribal affairs. That went on for about 20 years and then the politics of the 1950s came along and some people thought Indians living in their communal societies were too much like communists and they needed to be done away with, so they started terminating tribes – taking their land, selling it, moving Indians to the cities to be assimilated. This happened to about 100 tribes beginning in the '50s. And of course they didn't ask the tribes about that, they just did it. So in the 1960s and during the civil rights movement, our people started fighting back, complaining about this practice. In 1970 under President Nixon, he announced a national Native American policy that stopped termination and started recognizing tribal self-determination – the right of tribal nations to exist and manage their own affairs. So for the last 50 years that policy has stayed in effect and we have basically changed things. Our socioeconomic conditions are much better but still not as good as most people and we're still among the poorest of the poor. It's kind of a patchwork situation where some tribes do better than others. Has there been any lingering effect of trying to separate nations? Along the way, as you might guess, this was one of the first issues our board of directors had us address. One tribe, the Menominee Nation in Wisconsin, took their situation back to Congress and explained how that decimated their tribe, and asked Congress to admit they were wrong and to restore the Menominee Nation and their lands, and they did. And other tribes followed in their footsteps – those terminated tribes all went back (to their lands), one after another and all got restored. So Congress corrected its mistake. What are the greatest challenges facing Native Americans today, or is it even fair to try to lump all tribes as suffering the same issues? Different tribes have different issues. A lot of the challenges are lumped into those five priority issues that I mentioned. Overall, things are getting better. A lot of the reason for that is people understand we're still here. They just don't know about us but they're learning about us. They're learning that the United States is made up of federal government, state government and tribal government.

**You should not view the 1AC as a policy action as separate from the 1AC as a resistance project – only through embracing counter-hegemonic legal projects can we create new discourse and social meaning.**

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The core of orientalism is the capacity of the occident to claim to possess knowledge through which the orient is represented. In other words, since the nexus of knowledge is power, orientalism is about management and control of the orient by means of power (2003: 39). ***The creation of the current legal framework has created a fissure between the West and indigenous communities and can thus be interpreted as a conscious plan to deny power to indigenous communities through colonialism and apartheid.*** Said further contends that the orient and his world were seen as not existing in their own right, having life of their own, but rather as the extension of the European. It therefore would seem that orientalism was about diffusion of power from the centre, the West, towards the margins, the East, or in this case, Africa. Critical in this transaction were the West’s presumptions to claim knowledge of the orient by which they represented the orient. The ***orient is portrayed a ‘thing’, an ‘object’, and a ‘specimen’. Accordingly, he is someone who can be judged (as in a court of law), a subject matter to be studied (as in a curriculum) or examined, something to be disciplined (as in a school or prison), something one illustrates (as in a zoological manual).*** Furthermore, orientalism was strengthened by the knowledge that Europe or the West controlled the immense part of the earth surface (Said 2003). Subjugation of the orient did not merely entail land. It was intellectual and embraced within various discourses: Christian religion, sociology, ethnology, anthropology, politics and law. These explained the behaviour of orientals; they attributed to orientals a mentality, a genealogy, and an atmosphere; most importantly, they allowed Europeans to deal with and even see orientals as a phenomenon possessing regular characteristics. Nonetheless, the durability of orientalist notions was such that it influenced both the orientals as well as the European occident. This is the character of orientalism (2003: 2). 29 Rather than simply being a positive doctrine, at best it is understood as a set of constraints upon, and limitations to, not of thought. ***Orientalism presupposes and maintains that non-Europeans are irrevocably different from Europeans.*** More particularly the supposed inferior intellectual and physical abilities attributed to non-Europeans, so it was maintained, would make it impossible for them to attain cultural achievements similar to those achieved by their European counterparts. This notion was elaborated in various ways: for instance, technologically, it was assumed that it manifested in their inability to control nature; environmentally, it was held that their bodily constitution was compromised by the tropical climate. Postcolonial theory assists in trying to negotiate a new meaning of indigenous intellectual property ownership and current South African intellectual property laws by looking at how the subaltern or the indigenous communities consent to the domain of civil society through such channels as education, cultural practices and even intellectual property laws. This is non-liberative as the subaltern forgo their right to indigenous and communal ownership, as seen in the way the West has continuously plundered non-western materials and continued its political subjugation. The indigenous communities, according to orientalism, are consistently put at the service of colonial administration. In our case, indigenous knowledge is persistently put at the service of western knowledge systems and down played by western legal systems. The core of orientalism is the capacity by the West to claim possession of knowledge possessed by the orient. Therefore, orientalism will help us deconstruct and explain the transaction between indigenous knowledge systems and intellectual property laws as orientalism deals with how Europeans had power to manage and the orient or the indigenous communities over a significant period. Power to control did not only entail land. As stated earlier it was intellectual and it encompassed all aspects of life including law. ***The control by the West of intellectual property rights still exists since very little input from the indigenous communities has been solicited in the present intellectual property laws***. If they have been solicited the over riding paradigm is still Western and basically foreign in its approach. But even though the postcolonial theory helps us to look at the complex colonisation process, embedded in the postcolonial theory are cultural underpinnings which I shall look at in the next section. 30 2.3 Contested Cultures ***There is a critical need to assert how law and culture interact in our societies today. They are not independent of each other – they reinforce the hegemonic processes within communities. This investigation takes cognisance of a direct link between the law and indigenous cultural communities in the sense that even though cultural values might have not been factored into the current South African legal systems, the intellectual property law is alien in trying to address the needs of indigenous communities.*** Coombe (1998) notes legal forums are perceptibly significant locations for practices in which hegemony is constructed and then contested, providing institutional venues for struggles to establish and legitimate authoritative meanings. Law generates, then promotes, aspects of positivities, and at the same time it promotes prohibitions, legitimations, and oppositions to the subjects and objects, which it recognises. The resurgence of legal anthropology has contributed to the theoretical understandings of power, hegemony, and resistance (Comaroff 1995). With the rise of legal anthropology, prominence is then accorded to cultural milieu and: “Legal discourses are spaces of resistance as well as regulation, possibility as well as prohibition, subversion as well as sanction” (Coombe 1998: 25). There has been a rise of legal anthropology, which uplifts cultural aspects of communities; with rise in importance, the legal discourses become arenas on which new forms of legal systems may emerge. This process becomes vital in our study as it gives an opportunity for new forms of intellectual property protection to emerge based on the resurgence of legal and cultural anthropologies. Law is central to hegemonic process as stated earlier, but it is also a useful reservoir for counterhegemonic struggles. This is especially seen when the eminent realities are seized by those who in other instances might have versions of social relations formally consented to and other cultural meanings recognised. ***If indigenous communities can manage to change the current intellectual property laws, that is, deal with protection from their own cultural perspective, it is possible that overturning the understanding of intellectual property rights can bear some hegemonic consequences on the current social, political and economic relations and in turn new forms of ownership might be recognized.*** This then means that indigenous communities can be accorded an opportunity to contribute to the cultural, ideological and power struggles of the South African community. 31 Coombe continues to point out that ***law, then, is culturally explored “as discourse, process, practice, and system of domination and resistance” (1998: 26) to be connected to larger historical movements while remaining sensitive to the nuances of “the ontological and epistemological categories of meaning on which the discourse of law is based” (1998: 26). Historically structured and locally interpreted, law provides means and forums both for legitimating and contesting dominant meanings and the social hierarchies they support.*** Hegemony is an ongoing articulatory practice that is performatively enacted in juridical spaces where, as Susan Hirsch and Mindie Lazarus-Black put it, “webs of dominant signification enmesh at one level even those who would resist at another,” (1998: 26) and “hegemonic and oppositional strategies both constitute and reconfigure each other” (Comaroff 1995: 9). Legal situations usually shape the social meanings, which are assumed by signifying properties in public spheres. These social meanings are socially produced in fields which are typically seen by inequalities of digressing from subject to subject and material resources, symbolic capital, and access to channels of communication as Coombe expands: “if culture is our nature, whatever threatens to shut down, repress, or distort representation through the assertion of some absolute ‘presence’ threatens also to put an end to both culture and history” (1998: 26). ***Intellectual property rights currently formulated in our current context pose a threat to contemporary societal practices, invariably freezing forms, deeming denotation, and containing connotation.*** With the process of commodification of different cultural forms, there is a creation of new relations of power in contemporary cultural politics. With indigenous knowledge system it is hoped that it can play an important part in the creation of new power relations in South Africa. Its input will be a force to reckon and bargain with as many South Africans operate within its framework. For Coombe, laws ***legitimise and reinvigorate sources of “cultural authority by giving the owners of intellectual property priority in struggles to fix social meaning***” (1998: 26). If one draws examples principally from the field of trademark law of the cultural politics that engage commodified cultural signs in the condition of postmodernity, Coombe suggests that “the commodity/sign is always simultaneously participating in a poetics and a politics driven by social groups with differential abilities to influence the complexes of signifying forms within which they have agency” (1998: 26; 15 & 285). Cultural meanings are constantly contested. It is through this contest that indigenous knowledge can seek to have an upper hand and influence the discourse so that cultural 32 considerations from the indigenous communities can play a vital role in balancing the power relations which control the South African society. Coombe concludes by saying that increasingly, the holders of intellectual property rights are socially and juridically endowed with monopolies over the public meaning and the ability to be able to “control the cultural connotations of their corporate insignias (trademarks being the most visible signs of their presence in consumer culture). Intellectual property, then, is an arena for connotative struggle – ‘contested culture’” (1998: 26). It is against this background that I would like to examine intellectual property and its hegemonic role in cultural contestations. The existence of such laws intrinsically implies that certain communities by nature of their development have more latent power than other communities especially indigenous communities. There is a constant tension over this struggle, as indigenous communities would like to assert their control on the hegemonic process by claiming the importance of their indigenous intellectual property. On the one hand, it has been ignored and on the other hand, it has been exploited from the time of conquest till today.

#### Traditional Knowledge is the origin for innovation, but current formal systems are built to harm Indigenous peoples – only effective policy outcomes solve.

Bagley et al. ’17 [Margo Bagley is a CIGI Senior fellow and is the Asa Griggs Candler Professor of Law @ the Emory University School of Law, Ruth Okediji is the Traditional Knowledge Expert Group Chair and Jerimiah Smith Jr. Professor of Law @ Harvard Law School, Kathy Hodgson Smith is a Canadian Indigenous Lawyer and a member of the Métis Communities, Jerome Reichman is a CIGI Senior Fellow and the Bunyan S Womble Professor of Law @ Duke Law School, Graham Dutfield is a Professor of International Governance & Faculty of Law at Leeds University, the video is titled “What is Traditional Knowledge?”, the article is titled “What If a Patent Is Based on Traditional Knowledge?”, 06-12-2017, Centre for International Governance Innovation, evidence is transcribed from the video using the written subtitles , 0:00 – 1:45 ,https://www.cigionline.org/multimedia/what-if-patent-based-traditional-knowledge/]//pranav

Traditional knowledge in particular, represents innovation, it represents culture, it represents history, it represents the present, it represents the future. Traditional knowledge means different things to different people. It may relate to genetic resources, plants, animals, insects, that are native to the area where that particular community resides. Indigenous peoples have an insight into sustainable development and conservation and protection of biodiversity and that there’s something important in that, that we need to hear. When Indigenous people suffer from illnesses from microbes, what have they done to combat those illnesses? Have they used plants, have they used some food? These are clues to potential sources of medicine. What this project does at CIGI, is it makes visible the people and the cultures and the norms and the values that undergird the formal systems to which we pay so much attention, to the detriment sometimes of the people who historically have been the origin of much of the innovation and much of the knowledge that we enjoy and experience today. What we need to do in our Expert Group, is to ensure that evidence is made available and packaged in a way that can actually directly transfer into policy outcomes at these important forums in Geneva and elsewhere in the world.

#### Independently, these patents drive negative innovation – a practice where pharma companies are discouraged from improving their drugs and if they do only focus on helping those in rich wealthy countries. That begs the question of innovation for who?

Feldman et al. 8/10 [Robin C. Feldman - University of California Hastings College of the Law, David A Hyman - Georgetown University Law Center, W. Nicholson Price II - University of Michigan Law School, Mark J. Ratain - University of Chicago, “Negative innovation: when patents are bad for patients”, Nat Biotechnol 39, 914–916 (2021), https://doi.org/10.1038/s41587-021-00999-0]//pranav

Incentives in patent law have driven innovation into spaces that are affirmatively harmful to patients, and patentees are discouraged from taking steps to improve the product so as to prevent adverse health outcomes. Patent law in the United States is historically premised on advancing the interests of society. From the store of productive activity available to all, the government restricts some activities for a limited time in hopes this will redound to the benefit of all by incentivizing innovation1. The law thereby restricts competition, forgoing the concomitant advantages of the free market, but only during the patent period. After that time, the law expects that competition will enter, driving down prices and spurring new innovation. From this perspective, US patent law centers on the benefit to the public, with the inventor’s reward providing the vehicle for accomplishing this jurisprudential goal. In the health care space, these incentives have resulted in extraordinary success stories, but the same incentives can also result in a range of undesirable consequences, including excessive development of similar (but not better) products (‘me-too drugs’), the focus on drugs for diseases that affect wealthy people and wealthy countries rather than diseases that disproportionately affect the poor and developing nations, and a lack of innovation for types of medicines that may return fewer profits, such as antibiotics2,3,4. Similarly, drug companies will not research the utility of a known (and hence unpatentable) chemical, since the ability to obtain patent protection is central to their business model5. Past literature has highlighted these problems but has largely overlooked the problem of ‘negative innovation’, in which patent law drives innovation into spaces that are affirmatively harmful to patients. By this, we mean scenarios whereby patents create incentives to bring a product to market in a way that is relatively harmful to consumers, and the existence of a patent (and the associated rents) discourages the patentee from taking steps to improve the product so as to prevent the adverse health outcomes. Of course, there are other patent-driven situations of problematic utility, including scenarios that result in purely financial harms, such as drugs that are no better than existing options but are more expensive; scenarios where a small, heightened risk of direct physical harm is offset by lower prices for the drug in question6; and scenarios where there is no existing product on the market and inadequate incentives to develop such a product, so any physical harm is the result of the underlying disease or illness7. Finally, there is a general concern that inadequate new information about existing products is generated in the current system8. All of these scenarios are different in kind from negative innovation, which results in a harmful (but profitable) product. We focus on this dangerous but overlooked space of the patent landscape, wherein patents themselves lead fairly directly to patient harm. Ibrutinib, a small molecule drug discovered by Pharmacyclics (now a subsidiary of AbbVie), is an irreversible inhibitor of Bruton’s tyrosine kinase (BTK), a key regulator of B cell signaling and growth. It is approved by the US Food and Drug Administration for multiple indications and is most commonly used to treat B cell cancers, such as chronic lymphocytic leukemia. While ibrutinib is effective, it, like all anticancer agents, is toxic. It is all the more puzzling, then, that ibrutinib’s recommended dosage appears to be substantially higher than necessary to achieve the necessary therapeutic effect—or at least, what evidence is available points to that conclusion9. Problematic incentives created by the patent system make this result unfortunately unsurprising. The basic story is disheartening but simple. Early studies published by Pharmacyclics showed efficacy at low doses (partial response at 1.25 milligrams per kilogram body weight, approximately 40% response at 2.5 mg kg–1, and no relationship of response to dose between 2.5 and 12.5 mg kg–1)10. These reports were shared by Pharmacyclics in a conference abstract in 200911,12 and a press release in 201013. An early patent application by Pharmacyclics (US 2012/0087915 A1) accordingly claimed a full range of doses. Trials to support approval by the US Food and Drug Administration (FDA) continued. In July 2013, ibrutinib received accelerated approval for mantle cell lymphoma based on a 66% response rate in 111 patients treated at 560 mg daily. Notably, the 2013 FDA review included an analysis of the relationship of ibrutinib dose and trough plasma concentration to both response and toxicity. This analysis demonstrated no relationship with response: “Dose-response relationship for BTK occupancy and clinical response in the phase 1 dose escalation trial showed that maximum BTK occupancy and maximum response were achieved at doses of ≥ 2.5 mg/kg (≥ 175 mg for average weight of 70 kg)”14—far below the approved dosage of 560 mg. Meanwhile, the FDA also granted accelerated approval for previously treated chronic lymphocytic leukemia on 12 February 2014 on the basis of a 58% response rate in 48 patients treated at a dose of 420 mg daily. Thus, there were now two different doses approved for ibrutinib, with the labeled dose based solely on the dose that was used in the single-arm studies supporting the accelerated approvals. Furthermore, in the context of that approval, the FDA reiterated its assessment that the labeled dose was higher than necessary and included the explicit suggestion to study lower doses: “However, the proposed dose is 2.4-fold higher than the lowest dose that resulted in maximum BTK occupancy and maximum clinical response. Dose-response relationship for ORR and BTK occupancy from phase 1 study suggested that maximum ORR and maximum occupancy was achieved at doses of ≥ 2.5 mg/kg (≥ 175 mg for average weight of 70 kg) [see Pharmacometrics review in DARRTS dated 11/01/2013]. The sponsor should thus consider exploring lower doses in future development programs.”15 Those lower doses have not, to our knowledge, been rigorously explored in clinical trials—an unfortunate outcome for patients, since if a lower dose is just as effective with lower side effects, treatment would be safer and better. However, if the lower dose were found to provide better patient outcomes and resulted in a change in the labeled dose, it is likely that the labeled dose would not be covered by the patent. Thus, generic competitors might be able to enter the market sooner, once the primary compound patent lost exclusivity. In fact, the process at the US Patent and Trademark Office (USPTO) and the limits of the granted patents encourage the patent holder to avoid such information entirely. The patent examiner evaluating Pharmacyclics’ method of treatment patents found lower doses obvious on the basis of the 2009 and 2010 conference and press release disclosures, which occurred more than a year before the relevant patent was filed. Only the highest doses—420 mg and higher—were granted in the issued method of treatment patent16. Patent law thus created incentives to pursue a higher, more toxic dose rather than the lower doses the FDA suggested be explored. And, adding insult to injury, once the patent was issued with narrower claims covering the high doses only, the drug sponsor not only lacked incentives to explore the possibility of lower doses, it had an active incentive not to explore those doses because evidence that lower doses were safe and effective would sharply reduce the economic significance of the method of treatment patent it had narrowly managed to obtain. The patent holder already knew it could not get protection on a lower dose––the USPTO had rejected lower doses as obvious––so any evidence of the importance of lower doses would have undermined the value of the company’s patent-protected, higher-dose product. Although ibrutinib is only one example, we are concerned that it may be an indicator of a broader problem, one that either lies ahead or is already lurking. More generally, consider combination products with two drugs at fixed dosages. Many treatment method patents exist in which an independent claim specifies a dose, nominally designed to increase patient adherence but often at a much higher cost17,18. The result is that a prescriber cannot adjust the dosage for only one of the two drugs or discontinue only one component. It is possible, perhaps likely, that some of these combination regimens mirror the dosage issue with ibrutinib, in which the incentives of the patent system have encouraged the development of a drug in a form that is suboptimal for patient health in certain circumstances. This would not be the first time in history that combination medications have proven problematic. More than 50 years ago, a US Senate investigation found that certain combination antibiotics products—developed in an effort to bring something ‘new’ to the market—were useless or dangerous19. Nor is ibrutinib the only time in history that medications have been sold at higher dosages than appropriate for safety and efficacy. Millions of women received the birth control pill Enovid (mestranol/noretynodrel), containing ten times the necessary dose, before studies pointed to a concerning risk of blood clots19. In another sign of negative innovation, Gilead Sciences is alleged to have intentionally delayed a less-toxic version of its HIV medicine until just a few years before the original version’s patent expiration20. Unfortunately, the pernicious impact of patent incentives described above means that not only are these situations possible, but it is hard to know how frequent or how serious these situations are. Pharmacyclics did not follow the recommendation from the FDA and others to study lower doses. Because its method of treatment patents were tied to the higher dose, they had no economic incentive to do such research—any information on safer dosing outside the scope of the issued claims would undermine the value of their existing patent, and they would be unable to get a new patent for the safer dose on grounds of obviousness. The safety data are starting to emerge anyway, albeit from sources other than the company9.

#### also fuels monopolies stifling innovation.

Bryan Mercurio 14, Law Professor at The Chinese University of Hong Kong, “TRIPs, Patents, and Innovation: A Necessary Reappraisal?” <https://e15initiative.org/wp-content/uploads/2015/09/E15-Innovation-Mercurio-FINAL.pdf>

Identifying the factors that stimulate innovation is difficult (Lemley 2000), and attention must be paid to the different kinds of innovation--cumulative innovation; horizontal (basic) innovation; and vertical (applied) innovation. The impact of patent protection can differ on each of these types of innovation. For instance, where cumulative innovation occurs--that is, where a single product may rely on inventions owned by a number of firms--“there is good reason to think that the patent system may discourage innovation overall rather than encouraging it” (Bessen and Maskin 2009; Chu et al. 2012). Shapiro (2001) finds that “with cumulative innovation and multiple blocking patents, stronger patent rights can have the perverse effect of stifling, not encouraging innovation.” In such a situation, multiple licences have to be purchased; uncertainty regarding the status of the technology persists; and the value of patent licensing is questioned (Heller 2008; Boldrin and Levine 2008). Lawsuits become the norm; costs rise as firms defend claims and play the game by defensively purchasing patents; and innovation suffers (Boldrin and Levine 2013; Bessen and Muerer 2008). One only needs to look at the present situation in the high-tech sector to see this cycle playing out, where as much as US$20 billion was spent in 2010-11 on patent litigation and purchases, and where a “patent tax” of up to 20 percent of R&D costs exists (Duhigg and Lohr 2012). That a limited monopoly can stifle innovation should not come as a surprise given that competition is generally seen as a positive force in a market economy. Competition is widely thought to provide incentives for the efficient use of resources; motivation for constant progress; and protection for consumers (Vickers 1995). To some, there is an inherent contradiction between innovation and patent protection, as the latter impedes diffusion and obviates potential gains to be made from collaboration and competition (Rothbard 1962; Mises 1966; Palmer 1989; Lemley 2000; Stiglitz 2008). Thus, while Shumpeter acknowledges that competition for innovation led to temporary monopolies and argues that these monopolies were in turn replaced when new firms further innovated (1976), Stiglitz demonstrates that the established monopolies became entrenched as costs and externalities reduced incentives for displacement (Stiglitz and Walsh 2005). In turn, insufficient diversity among patent holders (a lack of so-called “equilibrium diversity”) encourages them to focus R&D on improving existing technologies through incremental improvements, as opposed to investing in R&D to develop new technologies and products (Acemoglu 2011).In essence, this is what the European Commission alleged in its prosecution of Microsoft for anti-competitive behaviour. There, the Commission deemed Microsoft to be a dominant player, which used its near-monopoly power to reduce “talent and capital invested in innovation” in a manner that “limits the prospects for ... competitors to successfully market innovation and thereby discourages them from developing new products” (2004). The negative effect on innovation is exacerbated by a number of factors, including the growing problem of patent thickets. Owing to the“difficulty of determining the boundaries” of patent claims, there are often multiple and competing claims over one or more aspects of an invention- -situations which, Stiglitz states, “especially impede innovation” (2008). While patent thickets have existed for more than a hundred years (a patent thicket impeded the development and commercialization of the airplane), they have more recently become particularly widespread in the electronics industry (GAO 2013). Other factors, such as defensive patenting and the extortion-like practices of socalled patent trolls, have likewise substantially increased the risk of net welfare loss and less innovation (Bessen et al. 2011; Tucker 2011). Recent studies even find that patent pool arrangements result in reduced innovation by member-firms (Lampe and Moser 2010; Joshi and Nerkar 2011; Lampe and Moser 2012). Evidence also exists to show that stronger patent protection leads not to enhanced innovation or an improvement in overall welfare, but to firms protecting their interests by advocating even more protection (Landes and Posner 2003). In so doing, firms divert resources away from R&D, and into lobbyists and lawsuits. Boldrin and Levine (2013) refer to this as the political economy effect, where patent protection keeps increasing due to the lobbying efforts of entrenched firms, and without regard to the system as a whole. In their view, such behavior distorts the optimum range of protection

and unbalances the entire system. In conclusion, while it is a certainty that patent protection increases patent applications and the number of patents granted, there is little to no solid evidence that it leads to increased innovation (Boldrin and Levine 2013; Scherer 2009; Lerner 2009; Gallini 2002; Jaffe 2000). Since the evidence suggests that “policy changes that strengthen patent protection … [do] not spur innovation” (Lerner 2002; UNCTAD 2011), it is unsurprising that “there is widespread unease that the costs of stronger patent protection may exceed the benefits” (Jaffe 2002). POTENTIAL RESPONSES To establish the economic significance and value of patents, it is necessary to weigh their social costs against their social benefits. Hall et al. (2012) explain, In principle a patent will function to increase fixed (and most likely sunk) costs of entry into a market where the invention protected by the patent is practiced. This will reduce entry and therefore competition. From a welfare perspective, this is the price society pays in order to encourage invention and innovation by the initial entrant. What results is a trade‐off between the interests of the incumbent holding the patent and the potential entrant excluded by it. In the case of patents, policy makers need to come to a view of how much protection to afford the patentee in order to create incentives for R&D. Given the trade-off between innovation and access, policy should be designed to reach the “optimal scope of IPRs protection”--that is, a “balance between the social benefit of innovation and the social cost of monopolistic distortion” (Nordhaus 1969). It is this balance that some believe is now lopsided. This section focuses on what can be done within the confines of the WTO to ensure that patent protection stimulates innovation and that the benefits are in balance with social costs. It goes beyond merely describing the available flexibilities offered by TRIPS to Members or analyzing the use of such tools. This work has been done (Mercurio 2013; Declaration on Patent Protection 2014), but does not go to the heart of the issue-- that of the link between IPRs and innovation. Moreover, given the definitional vagueness and uncertainty of the boundaries of patent claims and rights, countries have become risk averse and are unlikely to take action that may be viewed as inconsistent with the TRIPS Agreement. The discussion and debate must now move beyond the well-known but little used flexibilities to encompass the broader and more fundamental issue of whether IPRs--and correspondingly the TRIPS Agreement-- actually encourage innovation. In a sense, all the potential responses are radical in that they all require a shift from the status quo and amendment to the TRIPS Agreement. For this reason, none are likely to be feasible in the short, and perhaps even medium, term. This does not mean that potential responses should not be discussed. As the economic data and evidence against the current form and level of patent protection mounts, alternatives will become more realistic options. Radical proposals aimed at promoting innovation deserve to feature in the debate. The remainder of this section raises four alternatives to the status quo for discussion.